

Applicants' invention, as presented in amended independent claim 1, is directed to an implant comprising a body having an inner sheath and at least one outer sheath, each sheath being formed from a different bone and being formed with an exterior surface and an opening defining an interior surface, wherein the exterior surface of each outer sheath contacts the interior surface of no more than one other outer sheath.

Applicants' invention, as presented in amended independent claim 41, is directed to an implant comprising at least two layers of bone components coupled to each other, the components together defining at least one securing region, and at least one insertable securing element adapted for placement in the at least one securing region, wherein the implant is formed from at least two different bones.

Boyce is directed to a bone-derived implant for load-supporting applications. Boyce discloses a bone-derived implant 20 comprising alternating layers of fully mineralized cortical bone 22 and partially demineralized cortical bone 23. (Boyce, Col. 6, lines 1-3). Such a construction is explained in the specification of Boyce as follows:

The compression strength-imparting layer(s) of the bone-derived implant can be provided as monolithic sections of bone or as multi-sectional layers built up from two or more subsections, e.g., joined to each other in edge-to-edge fashion in a manner which is analogous to planking.

(*Id.*, Col. 2, lines 58-62).

Boyce is understood to be silent with respect to an implant formed of sheaths as recited in amended independent claim 1. The Office Action cites to Fig. 2 of Boyce as disclosing inner and outer sheaths. Applicants respectfully disagree. The alternating layers of cortical bone 22 and 23 in Fig. 2 of Boyce are not formed as sheaths. Moreover, none of the layers in Fig. 2 of Boyce is formed as a sheath with an opening defining an interior surface, as recited in Applicants' amended independent claim 1.

Boyce also is understood to be silent with respect to an implant comprising at least two layers of bone components coupled to each other as recited in Applicants' amended independent claim 41. In particular, claim 41 has been amended to recite that the implant is formed from at least two different bones.

With respect to dependent claims 14-15, 18 and 20 which depend from claim 1, and dependent claim 53 which depends from claim 41, it is submitted that these claims are patentable not only because of the patentability of the independent claim from which they respectively depend, but also for the totality of features recited respectively therein.

In the Office Action, claims 2, 5-13, 17, 19, 21-22, 25-39, 42-43, 48-52, and 54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Boyce. The Office

Action states that "Boyce discloses an alternative embodiment comprising a core disposed in the inner sheath (fig. 1)." (Office Action, Page 3, lines 5-6).

First, as a threshold matter, Fig. 1 of Boyce does not disclose an implant. On the contrary, Fig. 1 of Boyce shows the diaphyseal region (*i.e.*, the shaft region) of a bone 10. Furthermore, as described in the specification of Boyce, the cortical portion of bone 10 taken from the diaphyseal region is cut into cortical bone layers 11 of varying width by slicing the bone longitudinally. (Boyce, Col. 5, lines 62-65). Thus, Fig. 1 of Boyce fails to disclose, much less suggest, an embodiment of an implant as suggested in the Office Action.

Second, as previously discussed, the alternating layers of cortical bone 22 and 23 of Boyce are not formed as sheaths, as suggested in the Office Action.

Applicants' invention, as presented in independent claim 21, is directed to an implant comprising a body formed from a cross-section of a core and a plurality of sheaths with each sheath having an inner surface and an outer surface, wherein at least two sheaths are formed from different bones, the outer surface of a first sheath has about the same contour as the inner surface of a second sheath so that the first and second sheaths mate together, and the cross-section includes at least a portion of each sheath and core.

The Office Action states that Boyce discloses "a cross section of the sheaths and core." However, the Office Action fails to cite to any particular disclosure in Boyce. Boyce is understood to be silent with respect to a body formed from a cross-section of a core and a plurality of sheaths, as recited in independent claim 21.

It is submitted that claims 2, 5-13, 17 and 19 which depend from independent claim 1, claims 22 and 25-39 which depend from independent claim 21, and claims 42-43 and 48-52 which depend from claim 41 are patentable not only because of the patentability of the independent claim from which they respectively depend, but also for the totality of features recited respectively therein.

Finally, in the Office Action, claims 3-4, 16, 23-24, 40, and 44-47 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Boyce in view of U.S. Patent No. 4,950,296 to McIntyre ("McIntyre"). The Office Action stated:

Boyce discloses the invention substantially as claimed; however, Boyce does not disclose cancellous bone or bones selected from the femur, tibia, humerus, fibula, ulna, and radius. McIntyre teaches a bone implant comprising cancellous bone (col.3, lines 15-16) and bones selected from the femur, tibia, humerus, fibula, ulna, and radius.
(Office Action, Page 4, lines 5-9).

McIntyre is directed to bone grafting units comprising the combination of a cortical shell having a cavity and an outer shape and size for transplanting, and a cancellous plug fitted into said cavity. (McIntyre, Col. 1, line 68 - Col. 2, line 3).

Applicants' invention, as presented in amended independent claim 40, is directed to an implant comprising a plurality of sheaths each defining a hole, and a core fit in an innermost of the sheaths, wherein the sheaths are formed from at least two different bones selected from a femur, tibia, humerus, fibula, ulna, and radius.

As previously discussed, the alternating layers of cortical bone 22 and 23 of Boyce are not formed as sheaths, as suggested in the Office Action. Furthermore, McIntyre is understood to be silent with respect to an implant having a plurality of sheaths that are formed from at least two different bones. The combination of Boyce and McIntyre therefore is insufficient to render the implant of amended independent claim 40 obvious.

With respect to dependent claims 3-4 and 16 which depend from claim 1, dependent claims 23-24 which depend from claim 21, and claims 44-47 which depend from claim 41, it is submitted that these claims are patentable not only because of the patentability of the independent claim from which they respectively depend, but also for the totality of features recited respectively therein.

In view of the foregoing, it is believed that all the pending claims are in condition for allowance, which is respectfully requested. If the Examiner does not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues so as to expedite the eventual allowance of the claims.

A fee for an extension of time is believed to be due for this submission and a petition for extension of time is submitted concurrently herewith. Should any additional fees be required, please charge such fees to Pennie & Edmonds Deposit Account No. 16-1150.

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Respectfully submitted,

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Enclosures

EXHIBIT A - MARKED-UP VERSION OF AMENDED CLAIMS
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1. (Amended) An implant comprising a body having an inner sheath and at least one outer sheath, each sheath being formed from a different bone and being formed with [having an interior surface and] an exterior surface and an opening defining an interior surface, wherein the exterior surface of each outer sheath contacts the interior surface of no more than one other outer sheath.

40. (Amended) An implant comprising [a body having at least one sheath] a plurality of sheaths each defining a hole [with a core fit therein], and a core fit in an innermost of the sheaths, wherein the [body is] sheaths are formed from at least two different bones selected from a femur, tibia, humerus, fibula, ulna, and radius.

41. (Amended) An implant comprising at least two layers of bone components coupled to each other, the components together defining at least one securing region, and at least one insertable securing element adapted for placement in the at least one securing region, wherein the implant is formed from at least two different bones.